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No. OFFICE OF THE CLERK

**In the Supreme Court of the United States**

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APOTEX INC. AND APOTEX CORP.,

*Petitioners,*

v.

PFIZER INC.,

*Respondent.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS FOR THE  
FEDERAL CIRCUIT

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**PETITION FOR A WRIT OF CERTIORARI**

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February 9, 2006

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## **QUESTION PRESENTED**

This is one of many suits brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer.

The Question Presented is whether such a suit states a justiciable controversy when, as in this case, the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.

**LIST OF PARTIES**

All parties in the proceedings below are listed in the caption to this Petition.

**RULE 29.6 CORPORATE  
DISCLOSURE STATEMENT**

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

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## **OPINIONS BELOW**

The decision of the United States Court of Appeals for the Federal Circuit (App. 1a)<sup>1</sup> for which review by this Court is sought is available at No. 05-1199, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005). The decision of the United States District Court for the Southern District of New York that was reviewed by the Federal Circuit (App. 2a-15a) is reported at 385 F. Supp. 2d 187 (S.D.N.Y. 2005).

## **JURISDICTION**

The judgment of the Federal Circuit for which review by this Court is sought was entered on December 12, 2005. This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

## **CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED**

**U.S. Constitution, art. III, § 2, cl. 1** provides in pertinent part:

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; . . . .

(App. 69a.)

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<sup>1</sup> References to "App. \_\_\_\_" are to the Appendix attached hereto, as required under Supreme Court Rule 14.1(i).

**21 U.S.C.A. § 355(j)(5)(C)(i)(II)** (West Supp. 2005) provides:

**(C) Civil action to obtain patent certainty-**

**(i) Declaratory judgment absent infringement action-**

\* \* \*

**(II) Filing of civil action-** If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . .

(App. 70a-71a.)

**35 U.S.C.A. § 271(e)(5)** (West Supp. 2005) provides:

Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of

which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(App. 74a.)

### STATEMENT OF THE CASE

1. This petition arises from a patent dispute between respondent Pfizer and petitioner Apotex. Pfizer has patents relating to sertraline hydrochloride, which it sells as an anti-depressant under the brand-name Zoloft<sup>®</sup>, and which generates more than \$3 billion in annual sales. Apotex has developed a generic version of Zoloft<sup>®</sup> that it seeks to market.

Relevant here, Pfizer has listed with the FDA two patents in connection with Zoloft<sup>®</sup>: one expires in 2006 ("the '518 patent")<sup>2</sup>; the other ("the '699 patent"), which Pfizer has said expires in 2010. Apotex followed the statutory procedure for launching its generic equivalent to Zoloft<sup>®</sup>. It submitted to the FDA an Abbreviated New Drug Application (ANDA). Apotex represented that it would begin selling its drug after the '518 patent expired in 2006.

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<sup>2</sup> The '518 patent actually expired on December 30, 2005, but Pfizer obtained a 6-month regulatory exclusivity period attaching to that patent. See 21 U.S.C. § 355a. That period ends on June 30, 2006.

Apotex further represented that the later-expiring '699 patent would not be infringed or was invalid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "Paragraph IV certification").

Pfizer previously has been quite aggressive in defending its intellectual property. It did not, however, sue Apotex precisely in order to prevent the marketing of a generic equivalent to Zoloft<sup>®</sup>. See 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(2)(A) (making the submission of a Paragraph IV certification a statutory act of patent infringement). The failure to resolve the patent controversy specifically created a substantial cloud of uncertainty over Apotex's ability to enter the marketplace because Apotex faced potentially crippling patent liability. In addition, the failure to secure a court judgment of non-infringement or invalidity precluded Apotex as a matter of law from selling its drug until *at least* 180 days after the expiration of the '518 patent.<sup>3</sup>

Congress has enacted a statutory scheme specifically designed to prevent brand-name manufacturers from delaying generic market entry with such tactics. Federal law

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<sup>3</sup> Apotex will be delayed at least 180 days after expiration of the '518 patent. Federal law grants the first generic manufacturer to file an ANDA containing a Paragraph IV certification (in this case, Ivax Pharmaceuticals) the right to sell its products as the only generic competitor for 180 days. See 21 U.S.C. § 355(j)(5)(B)(iv). If Apotex secured a judgment that the '699 patent was invalid or not infringed, the expiration of the 180-day period for that patent would begin to run immediately, rather than upon Ivax's first commercial marketing. *Id.* But because, absent a court decision on the '699 patent, Ivax's exclusivity will not begin to run until it begins marketing its product, Apotex could be precluded from marketing far longer than 180 days after the '518 patent expires. This would happen if Ivax, for any reason, decided not to immediately begin marketing its product on June 30, 2006.

provides that Pfizer's submission of the '699 patent to the FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" based on this patent against a generic competitor. 21 U.S.C. § 355(b)(1). Further, Apotex's filing of its Paragraph IV ANDA constituted a statutory act of patent infringement of the '699 patent. 35 U.S.C. § 271(e)(2)(A). In such circumstances, Congress specifically conferred on the federal courts jurisdiction over a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II)) and directed that such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).

2. Apotex accordingly brought this declaratory judgment suit against Pfizer in the Southern District of New York alleging that its generic equivalent would not infringe the '699 patent or that the '699 patent was invalid. The district court acknowledged that Pfizer had represented that the '699 patent was enforceable against generic equivalents of Zolof<sup>®</sup>, whereas Apotex took the opposite position and submitted an ANDA that constituted a statutory act of patent infringement. (App. 6a-7a.) And the district court did not doubt that Apotex's inability to enter the marketplace based upon a failure to resolve the patent controversy injured Apotex. Indeed, the district court recognized this "gaming of the system" by brand-name manufacturers. (App. 4a.) The practice of companies such as Pfizer of "'parking' the 180-day marketing exclusivity period" has the effect of "indefinitely delaying" generic competition. (App. 5a.) Congress had specifically conferred on generic manufacturers the right to sue, and the obligation of the federal courts to resolve those actions, "[t]o curb these abuses." (*Id.*)

The district court nonetheless held that it was required by Federal Circuit precedent to dismiss the suit for lack of a justiciable case or controversy because Apotex did

not have a "reasonable apprehension" that it would be sued by Pfizer. (App. 12a-15a.)

3. The Federal Circuit had exclusive jurisdiction over Apotex's appeal. 28 U.S.C. § 1295(a)(1). While the appeal was pending, that court decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (App. 16a-49a), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005) (App. 50a-68a), *and cert. denied*, 126 S. Ct. 473 (2005). *Teva* concerned the justiciability of another manufacturer's declaratory judgment action against Pfizer regarding this same drug product – a generic competitor to Zolofit<sup>®</sup>. *Teva*, joined by AARP and the Federal Trade Commission as *amicus curiae* (see [http://www.ftc.gov/ogc/briefs/teva\\_v\\_pfizer.pdf](http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf)), argued that a justiciable case or controversy existed on these recurring facts.

A divided panel of the Federal Circuit, tightening its already rigorous requirement for finding a justiciable case or controversy, held that a court may adjudicate a declaratory judgment action only if the generic competitor faces an "imminent" suit by a brand-name manufacturer. *Teva*, 395 F.3d at 1333 (App. 30a). Like the district court in this case, the Federal Circuit in *Teva* did not doubt that a generic manufacturer is directly and immediately injured by this state of affairs. Rather it was dispositive that "Teva virtually concedes that Pfizer will not bring immediate suit" because it "does not wish to expose the patent to the possibility of a noninfringement or invalidity determination." *Id.* at 1333-34 (App. 31a).

The Court simply deemed irrelevant as a matter of law the clear and actual controversy between the parties and the concrete injury suffered by Teva:

The fact that Teva is disadvantaged from a business standpoint . . . and the fact that Pfizer's decision not to sue Teva creates an

impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

395 F.3d at 1338 (App. 40a) (emphasis added). It continued:

[I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage . . . . Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

*Id.*

Teva, again joined by the FTC as *amicus curiae* (see <http://www.ftc.gov/ogc/briefs/050208teva.pdf>), sought rehearing en banc. The court of appeals denied rehearing by a divided vote and over vigorous dissenting opinions. *Teva*, 405 F.3d at 991-96 (App. 52a-61a) (Gajarsa, J., dissenting); *id.* at 996-99 (App. 61a-68a) (Dyk, J., dissenting).<sup>4</sup>

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<sup>4</sup> In response to Teva's petition for certiorari, Pfizer argued that no controversy existed on the facts of that particular case for a unique

4. Pfizer argued that this appeal was controlled by the Federal Circuit's ruling in *Teva*. The court of appeals agreed and summarily affirmed the judgment dismissing Apotex's suit. (App. 1a.)

### **REASONS FOR GRANTING THE WRIT**

The Federal Circuit's holding that manufacturers such as Apotex are forbidden from filing a declaratory judgment action, pursuant to the Federal law enacted for this precise purpose, merits this Court's review. That ruling cannot be reconciled with this Court's precedents interpreting the case or controversy requirement of Article III. The question is, moreover, of indisputable importance not only to the generic pharmaceutical industry, but also to the public, which relies so heavily on that industry to provide lower-priced versions of life-saving drugs. Accordingly, this Court should grant certiorari. At the very least, the Court should invite the Solicitor General to file a brief expressing the views of the United States on this critically important issue.

#### **I. The Federal Circuit's Decision Elevates The "Reasonable Apprehension" Test To A Constitutional Standard, In Direct Conflict With This Court's Precedents.**

The Federal Circuit's decision impermissibly elevates that court's prudential jurisdictional doctrine (the

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reason. After the Federal Circuit's ruling, Teva had agreed to merge with Ivax, such that Teva might never separately market its own generic Zolofit<sup>®</sup> product. See Pfizer's Br. in Opp'n at 10, 11, 23, 25 (No. 05-48). Teva did not dispute that fact. See Teva Reply Br. at 4 (No. 05-48). This Court subsequently denied certiorari. See *Teva Pharms. USA, Inc. v. Pfizer*, 126 S.Ct. 473 (2005).

“reasonable apprehension” requirement) to a “constitutional requirement.” See *Teva Pharms.*, 395 F.3d at 1335 (App. 33a). That standard cannot be reconciled with a wall of this Court’s precedent, which does not impose such a requirement, but rather holds to the contrary, holding that Article III requires no more than a redressible injury-in-fact traceable to the declaratory judgment defendant’s conduct.

It is well-established under this Court’s controlling precedent that the only prerequisite to jurisdiction under the Declaratory Judgment Act is an “actual controversy” under Article III, which merely requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 167 (1997); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239-40 (1937); see also *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 103-04 (1998); *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95-96 (1993).

*Cardinal Chemical Co. v. Morton International, Inc.*, for example, addressed the circumstances in which Article III permits a declaratory judgment action with respect to a patent infringement claim. 508 U.S. 83. Recognizing that “a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy,” this Court explained that “[i]n patent litigation, a party may satisfy that burden; and seek a declaratory judgment, even if the patentee has not filed an infringement action.” *Id.* at 95. The Court quoted with approval Judge Markey’s recognition in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988), that cases such as this present

the sad and saddening scenario that led to enactment of the Declaratory Judgment Act . . . In the patent version of that scenario, a patent owner engages in a *danse macabre*,

brandishing a Damoclean threat with a sheathed sword. . . . Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the *patent owner refused to grasp the nettle and sue*. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests. *The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.*

*Cardinal Chem.*, 508 U.S. at 95-96 (quoting *Arrowhead Indus. Water*, 846 F.2d at 734-735) (emphasis added).

Indeed, this Court's seminal ruling "upholding the [declaratory judgment] statute" – *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937) – arose from an indistinguishable context "in which there was no imminent risk of suit because the potential plaintiff declined to sue." *Teva*, 405 F.3d at 996 (App. 63a) (Dyk, J., dissenting). In *Aetna*, an insurer filed a declaratory judgment action regarding its obligations to the policyholders. Aetna sued precisely because the policyholders had "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability." 300 U.S. at 239. This Court held Article III satisfied in light of the "definite and concrete" dispute relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be

appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 241.<sup>5</sup> The criteria set forth by this Court's precedents are easily satisfied in the recurring factual circumstances of this case.

In listing the '699 patent with the FDA, Pfizer formally took the position that generic competitors were subject to suit for infringement of that patent if they marketed prior to its expiration. Apotex seeks to market its generic product before the '699 patent expires, maintaining that its product would not infringe the '699 patent or that the patent is invalid. Apotex currently is injured by virtue of Pfizer's conduct. As an initial matter, Apotex cannot enter the marketplace immediately upon expiration of the '518 patent because FDA cannot approve Apotex's product until Ivax's 180-day exclusivity expires. Should Ivax delay marketing after the '518 patent expires, Apotex's market entry will be further delayed.

Moreover, the very possibility of debilitating patent liability could further delay Apotex from entering the market. Infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs, such as Zoloft<sup>(R)</sup>, would ruin most generic companies. As a result, few generic companies can risk going to market

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<sup>5</sup> Given the statutory command to exercise jurisdiction to the fullest constitutional limits (*see* 35 U.S.C. § 271(e)(5)), the question of whether petitioner's suit satisfies Article III is dispositive of whether it satisfies any statutory or prudential standing requirement. The suggestion of the *Teva* majority that the legislative history supports a narrower reading of the statute, 395 F.3d at 1336-37 (App. 35a-38a), obviously cannot be reconciled with the statutory text. In any event, as discussed in the text, the Federal Circuit's decision is directly contrary to the purposes of the statutory scheme.

before a final judicial resolution of their patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows these companies to continue selling drugs at monopoly prices while generic companies struggle to obtain the certainty that they need to launch free from fear of patent infringement liability.

Not even the Federal Circuit majority in *Teva* doubted that generic manufacturers such as Apotex suffer an "injury" in the factual scenario at issue here. 395 F.3d at 1338 (App. 40a). That court simply deems irrelevant as a matter of law that the competitor "is disadvantaged from a business standpoint" and "finds itself at a competitive disadvantage." *Id.* That view is insupportable, as Judge Mayer recognized, dissenting in *Teva*:

Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.

395 F.3d at 1343 (App. 49a).

Notably, the Federal Trade Commission strongly concurs. "The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays [generic competitors] from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against [the competitor]." FTC *Teva En Banc* Br. 9. "Absent such a decision," every generic competitor "must

wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that [a competitor] can advance the date of the approval of its product is through this litigation. Absent this action, [the competitor] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." FTC *Teva* Panel Br. 21-22.

The Federal Circuit originally adopted its "reasonable apprehension" test for "pragmatic" reasons (*EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996)) that simply do not apply here. It sought to "protect[] quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead Indus. Water*, 846 F.2d at 736. But "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." FTC *Teva* Panel Br. 13. To the contrary, the Federal Circuit in *Teva* recognized that Pfizer declined to file suit to prevent generic competition, not because of ambivalence about its patent rights. 395 F.3d at 1333-34, 1338 (App. 31a). The reasonable apprehension test is simply "ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." FTC *Teva* Panel Br. 12.<sup>6</sup>

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<sup>6</sup> Conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" also are "useful in identifying questions that merit this Court's attention." *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring). This Court accordingly has reviewed Federal Circuit decisions when "other courts have held or assumed" the contrary. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). It therefore bears noting that, in the period that the regional circuits had jurisdiction over patent appeal, they faithfully adhered to this Court's declaratory judgment precedents. The Eighth and District of Columbia Circuits found a justiciable

## II. The Federal Circuit's Decision Seriously Undermines Congress's Determination to Enhance Generic Pharmaceutical Competition for The Benefit of the American Public.

The Federal Circuit's error is all the more grave because it effectively nullifies an entire statutory scheme. Congress enacted the declaratory judgment provisions invoked by Apotex in this case for the express purpose of permitting suits, such as Apotex's, to go forward in order to ensure that the American public had access to essential, less-expensive generic equivalents.

Before the 1984 Hatch-Waxman Amendments, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to the FDA. And because such testing can, and often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension. See generally Susan Kopp Keyack, *The Drug Price Competition and Patent Term*

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controversy whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one*, a standard met here in light of Pfizer's representation that the '699 patent could be invoked as a basis for patent infringement. See, e.g., *United Christian Scientists v. Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). Notably, these circuits accorded weight to the fact that the patentee has previously brought infringement actions. See *Sherwood Med.*, 512 F.2d at 728; *United Christian Scientists*, 829 F.2d at 1158 n.25.

*Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 153-54, 160-61, 165 (1989); Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & HEALTH 111, 115-16 (1991/1992).

In 1984 and again in 2003, Congress amended the statute in numerous respects in order to speed generic competition. Congress provided that: (a) a brand-name manufacturer's submission of a patent to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" (21 U.S.C. § 355(b)(1)); (b) the filing of an ANDA claiming patent non-infringement or invalidity constitutes a statutory act of patent infringement (35 U.S.C. § 271(e)(2)(A)); (c) federal courts have jurisdiction over such a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5)); and (d) such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).<sup>7</sup>

Through this scheme, Congress sought to "enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Congress correctly recognized the substantial national interest in getting "generic drugs into the hands of patients at reasonable prices—fast" (*In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), and specifically sought to

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<sup>7</sup> Congress also specifically overturned the Federal Circuit's holding that any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement (*see Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861-63 (Fed. Cir. 1984), *superseded by* 35 U.S.C. § 271(e)(1)), which was a principal source of brand name manufacturers' *de facto* patent term extensions.

ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies" (H.R. CONF. REP. NO. 108-391, at 836 (2003)). To effectuate that goal, Congress enacted the declaratory judgment provisions to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 CONG. REC. S15,746 (Nov. 24, 2003).

The Federal Circuit's excessively restrictive test for recognizing a justiciable case or controversy accordingly will have far-reaching, negative consequences for generic pharmaceutical companies and the American public that depends upon generic companies like Apotex to bring more affordable drugs to market. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. The Federal Circuit's ruling encourages brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." *Teva*, 405 F.3d at 994-95 (App. 59a) (Gajarsa, J., dissenting).

Thus, the Federal Circuit's decision, by misapplying this Court's precedent, cripples generic competition by leaving generic companies like Apotex under a debilitating cloud of patent uncertainty and outright precludes marketing for a substantial period. Consequently, it seriously undermines congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States.

Brand-name manufacturers routinely employ the tactics used by Pfizer in this case to delay competition. A perfect example is Pfizer's conduct with respect to the drug Accupril<sup>®</sup>, for which Apotex also submitted an ANDA. As in this case, Pfizer asserted its patent against only the first ANDA filer (in that case, Teva). Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its own generic equivalent. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). But when another generic competitor (Ranbaxy) entered the market, exposing itself to massive damages, Pfizer promptly filed suit. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, Case No. 05-cv-00620(DRD) (D.N.J.). While several other companies have FDA approval to begin marketing their own generic Accupril<sup>®</sup> products, the threat of litigation has significantly delayed generic entry. Thus, brand companies like Pfizer have, in effect, created a new "de facto" exclusivity period in direct contravention of Congress's express intent.

The consequences for the American public are substantial. As the Federal Trade Commission advised the Federal Circuit, "declaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that *no* generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." FTC *Teva* Panel Br. 8 n.9 (emphasis added).

The high costs of brand-name prescriptions are a significant barrier in most cases to proper medical treatment for many Americans, particularly the elderly. *See AARP, Prescription Drug Costs and the Role of Generic Drugs: Public Opinion Among Americans Aged 45 and Over 2* (Oct. 1, 2002) ("[N]early one in four Americans 45 and older

(24%) reported *not* being able to afford a prescription drug because no generic version was available.”). Because generic drugs are sold for a fraction of the prices of their brand-name counterparts, access to generic pharmaceuticals is “perhaps the single most important route to lower personal and national drug costs during the next decade.” Steven Findlay, *Easy Way to Cut Costs of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A.

As the FDA Commissioner has explained, generic drugs “are an increasingly important way to provide the American people with safe, effective and affordable medical treatment.” *Generics: FDA Announces Measures to Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 239; see also National Institute for Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002) (suggesting that the “advent” of generic anti-depressant drugs “may help rectify” “a persistent under-diagnosis and under-treatment of depression in the U.S.”). The cost savings resulting from the availability of generic drugs is inescapable. Indeed, the substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year, without compromising safety or health.<sup>8</sup> Jennifer S. Haas, *et al.*,

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<sup>8</sup> A recent study published in the ANNALS OF INTERNAL MEDICINE, concluded that “broad generic substitution of outpatient prescription drugs could save approximately \$8.8 billion, or approximately 11% of drug expenditures for adults . . . in the United States each year.” Jennifer S. Haas, *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 894 (June 7, 2005); see also Food and Drug Administration, *FDA White Paper: New FDA Initiative on “Improving Access to Generic Drugs”* (June 12, 2003), available at <http://www.fda.gov/oc/initiatives/generics/whitepaper.html>

*Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 895 (June 7, 2005) (indicating that “[b]road dispensing of generic products would achieve savings without compromising safety,” because “[g]eneric drugs are believed to provide therapeutic effects similar to those of their brand-name alternatives”); Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), available at <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (recognizing that “Americans need generic drugs more than ever” and that “[b]ringing low-cost generic drug alternatives to consumers more quickly can significantly reduce overall health care costs, and increase access to life saving medicines that are just as safe and effective as their brand-name counterparts”).

Thus, the decision of the Federal Circuit will have far-reaching negative effects on the American public, as it inevitably and unnecessarily delays access to these lower-cost generic drugs.

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(reporting that the average price of a brand-name drug is \$72, compared with \$17 for its generic counterpart).

**CONCLUSION**

The petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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February 9, 2006

**Appendix A – Opinion of the  
United States Court of Appeals for the Federal Circuit in  
*Apotex, Inc. v. Pfizer Inc.* (No. 05-1199)  
Filed December 12, 2005**

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**UNITED STATES COURT OF APPEALS FOR THE  
FEDERAL CIRCUIT**

No. 05-1199

APOTEX, INC. and APOTEX CORP., Plaintiffs-Appellants,

v.

PFIZER INC., Defendant-Appellee.

December 12, 2005.

On Appeal from the United States District Court for the  
Southern District of New York, 04-CV-02539.

Before LINN, DYK, and PROST, Circuit Judges.

Judgment

PER CURIAM

This CAUSE having been heard and considered, it is  
ORDERED and ADJUDGED:  
*AFFIRMED.* See Fed. Cir. R. 36.

**Appendix B – Opinion of the  
United States District Court for the Southern District of  
New York in *Apotex, Inc. v. Pfizer Inc.* (No. 04-2539),  
Granting Defendant's Motion to Dismiss  
Filed January 3, 2005**

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

No. 04 Civ. 2539(DC)

APOTEX, INC and APOTEX CORP., Plaintiffs,

v.

PFIZER INC., Defendant.

January 3, 2005.

CHIN, District Judge.

In this patent case, plaintiffs Apotex, Inc. and Apotex Corp. (together, "Apotex") bring a declaratory judgment action for a determination that their generic drug does not infringe U.S. Patent No. 5,248,699 ("the '699 patent"), held by defendant Pfizer Inc. ("Pfizer"). Pfizer moves to dismiss the action, arguing that the Court lacks subject matter jurisdiction because of the absence of an actual controversy between the parties. For the reasons that follow, the motion is granted and the complaint is dismissed, without prejudice.

## BACKGROUND

### *A. Regulatory Background*

#### *1. Hatch-Waxman Amendments*

This dispute arises under a series of amendments to the Federal Food, Drug, and Cosmetic Act of 1938 (the "FDCA"), 21 U.S.C. § 1 *et seq.* The "Hatch-Waxman Amendments," enacted as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), simplified Food and Drug Administration ("FDA") procedures for the approval of generic drugs. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). Under the Hatch-Waxman Amendments, companies that want to market generic versions of pioneer drugs may file with the FDA an Abbreviated New Drug Application ("ANDA"), relying on the FDA's prior determinations that the pioneer drug was safe and effective. See 21 U.S.C. § 355(j)(2)(A); see generally *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502 (D.N.J. 2004).

A pioneer drug manufacturer is required to notify the FDA of all patents that cover the pioneer drug. 21 U.S.C. § 355(b)(1), (c)(2). These patents and their expiration dates are listed by the FDA in what is commonly known as the "Orange Book"—the "Approved Drug Products With Therapeutic Equivalence Evaluations." For all applicable patents listed in the Orange Book, ANDA applicants must certify whether the generic drug would infringe the patents. 21 U.S.C. § 355(j)(2)(A)(vii). Specifically, the ANDA applicant may certify that (I) the required patent information has not been submitted to the FDA; (II) the patent has

expired; (III) the patent has not expired but is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications. See generally *Andrx Pharms., Inc.*, 276 F.3d at 1371.

If an ANDA applicant makes a paragraph IV certification and the patent holder (the pioneer drug company) sues for patent infringement within forty-five days, the FDA may not approve the ANDA until expiration of the patent, a judicial determination that the patent is invalid or not infringed, or thirty months, whichever is earlier. If the patentee does not sue, the ANDA will be approved. 21 U.S.C. § 355(j)(2)(B)(I), (5)(B)(iii); 21 C.F.R. § 314.95(c)(6).

The first applicant to file an ANDA with a paragraph IV certification is a “first filer,” and is eligible for a 180-day exclusivity period during which it is entitled to have the sole generic version of the pioneer drug on the market. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA is prohibited from approving any other ANDA involving the same brand name drug until the end of the exclusivity period, *i.e.*, during that period only the brand name manufacturer and the first filer may market that drug. *Id.* The marketing exclusivity period does not begin immediately upon FDA approval of the first ANDA, but rather upon the earlier of (1) the first commercial marketing of the drug, or (2) the date of a court decision declaring the patent invalid or not infringed. *Id.*

While the Hatch-Waxman framework “has saved billions and billions of dollars for consumers[,] ... there [has been] a gaming of the system” by some brand name drug companies. 149 Cong. Rec. S15563 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch); see Congressional Budget Office, “How

Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” 27-31 (July 1998). Some brand name drug manufacturers have succeeded in “parking” the 180-day marketing exclusivity period, indefinitely delaying ANDA approvals and bottlenecking the market. Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration,” vi-vii (July 2002). “Parking” occurs when the brand name manufacturer convinces the first filer not to enter the market, often through a settlement agreement concluding a patent infringement suit. *Id.* Absent an intervening court decision, the first filer’s failure to enter the market delays the triggering of the 180-day exclusivity period so that it neither begins nor ends, and subsequently filed ANDAs cannot be approved. *Id.*

## **2. Medicare Amendments**

To curb these abuses, Congress added another round of amendments to the FDCA in the comprehensive Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Medicare Amendments”). Pub. L. No. 108-173, 117 Stat. 2066 (2003). The Medicare Amendments established forfeiture provisions to prevent bottlenecking and revised sections of the patent code authorizing declaratory judgment actions by ANDA filers. *Id.* In particular, Congress provided that “the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction” in any declaratory judgment action by a generic manufacturer who (1) has filed an ANDA with a paragraph IV certification and (2) was not sued by the NDA holder within the forty-five day statutory period. 35 U.S.C. § 271(e)(5).

## **B. Facts**

### **1. Pfizer**

Pfizer markets Zoloft<sup>®</sup>, the brand name version of setraline hydrochloride approved by the FDA for the treatment of mood and anxiety disorders. Pfizer has listed Zoloft<sup>®</sup> in the Orange Book, associating it with the '699 patent and U.S. Patent No. 4,356,518 ("the '518 patent"). The '699 patent will expire on September 28, 2010, and the '518 patent will expire on June 30, 2006.

### **2. IVAX**

In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as IVAX, filed the first setraline hydrochloride ANDA. IVAX submitted a paragraph IV certification with respect to the '699 patent, *i.e.*, it asserted that the '699 patent was invalid or not infringed by IVAX's product, and a paragraph III certification with respect to the '518 patent, *i.e.*, it asserted that IVAX will not enter the market until the expiration of the '518 patent on June 30, 2006. As the first filer, IVAX was entitled to a 180-day marketing exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv). Pfizer responded within forty-five days of receiving notice of the ANDA, initiating a patent infringement action against IVAX in January 2000. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the suit automatically suspended FDA approval of the IVAX ANDA for thirty months. The parties reached a settlement in May 2002 that provided that IVAX would receive a license to the '699 patent and may begin marketing setraline hydrochloride by June 30, 2006.

### **3. Apotex**

On October 27, 2003, Apotex filed an ANDA seeking the FDA's approval to market its version of setraline hydrochloride. Like IVAX, Apotex filed a paragraph III certification with respect to the '518 patent and a paragraph IV certification with respect to the '699 patent. Pursuant to the Hatch-Waxman framework, the FDA cannot approve the Apotex ANDA until 180 days after IVAX enters the market or a court decision decrees the '699 patent invalid or not infringed, whichever is earlier. If neither event occurs, the Apotex ANDA cannot be approved until September 2010, when the last Zoloft-related patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(ii).

### **4. Other ANDA Filers**

In addition to IVAX and Apotex, at least six other generic drug manufacturers have filed ANDAs for setraline hydrochloride; Pfizer has initiated suit against none of them. (Myers Decl. ¶ 9). Two of these companies, Teva Pharmaceuticals USA, Inc. and Dr. Reddy's Laboratories, Ltd., filed ANDA-related declaratory judgment actions against Pfizer, as Apotex has done here. (Def.'s Mem. at 7-8). Both cases were dismissed for lack of subject matter jurisdiction. *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03-CV-10167 (RGS), 2003 WL 22888848, at \*1 (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. 03-CV-726 (JAP), 2003 WL 21638254, at \*7 (D.N.J. July 8, 2003).

### **C. Procedural History**

Apotex filed its complaint on April 1, 2004. On June 22, 2004, Pfizer moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. Pfizer argues that this Court does not have subject matter jurisdiction

because of the absence of an actual controversy, as required by the Declaratory Judgment Act. 28 U.S.C. § 2201(a). Apotex contends that there is such a controversy. For the reasons that follow, the motion to dismiss is granted.

## DISCUSSION

### ***A. Applicable Law***

#### ***1. Motion to Dismiss Standard***

In considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), federal courts “need not accept as true contested jurisdictional allegations.” *Jarvis v. Cardillo*, No. 98 Civ. 5793(RWS), 1999 WL 187205, at \*2 (S.D.N.Y. Apr. 5, 1999). Rather, a court may resolve disputed jurisdictional facts by referring to evidence outside the pleadings. *Zappia Middle E. Constr. Co. v. Emirate of Abu Dhabi*, 215 F.3d 247, 253 (2d Cir. 2000); *Filetech S.A. v. France Telecom S.A.*, 157 F.3d 922, 932 (2d Cir. 1998). As the party “seeking to invoke the subject matter jurisdiction of the district court,” plaintiff bears the burden of demonstrating that there is subject matter jurisdiction in this case. *Scelsa v. City Univ. of New York*, 76 F.3d 37, 40 (2d Cir. 1996).

#### ***2. Subject Matter Jurisdiction***

Subject matter jurisdiction under the Declaratory Judgment Act requires the existence of an actual case or controversy: “The Declaratory Judgment Act permits declaratory relief only in cases presenting ‘actual controversies,’ ... a requirement that incorporates into the statute the case or controversy limitation on federal jurisdiction found in Article III of the Constitution.” *Niagara Mohawk Power Corp. v.*

*Tonawanda Band of Seneca Indians*, 94 F.3d 747, 752 (2d Cir. 1996) (citing 28 U.S.C. § 2201(a)).

### ***3. The Reasonable Apprehension Test***

In declaratory judgment actions for patent invalidity or non-infringement, the courts have applied a two-part test to determine whether an "actual controversy" exists:

There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

*Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1481 (Fed. Cir. 1998). The first prong of this inquiry examines the defendant's conduct, while the second prong focuses on the plaintiff's conduct. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). This two-part test has become known as the "reasonable apprehension" test.

To determine whether there is a reasonable apprehension that the defendant will sue for patent infringement, courts apply an objective test that focuses on the conduct of the defendant and attempts to ascertain whether a defendant has shown an intent to enforce its patent rights. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992); *Arrowhead*, 846 F.2d at 736. Such an intent is readily exhibited with express accusations of infringement and threats to bring suit. Explicit threats, however, are not required to create a reasonable apprehension. *EMC Corp. v. Norand Corp.*, 89

F.3d 807, 811 (Fed. Cir. 1996). “In light of the subtleties in lawyer language ... the courts have not required an express infringement charge,” *Arrowhead*, 846 F.2d at 736, finding instead that “reasonable apprehension ... may be induced by subtler conduct.” *EMC Corp.*, 89 F.3d at 811.

In the absence of overt threats, the “totality of the circumstances” must be considered in evaluating whether a reasonable apprehension of infringement litigation exists. *Arrowhead*, 846 F.2d at 736. In other words, the court must look at the full range of the defendant’s conduct and determine whether those actions, considered in context, create a reasonable apprehension. *Consac Indus., Inc. v. Nutramax Labs., Inc.*, No. 97 Civ. 1155(SJ), 1998 WL 229255, at \*3 (E.D.N.Y. Mar. 31, 1998).

#### **4. The Medicare Amendments**

Apotex argues that the reasonable apprehension test is “legally irrelevant,” contending that it no longer applies because of the Medicare Amendments passed in 2003. (Pl.’s Mem. at 7). Instead, Apotex argues, the Medicare Amendments expressly authorize an ANDA-filer to bring a declaratory judgment action where, as here, a patentee does not file suit within the forty-five day period. (*Id.* at 8) (citing 21 U.S.C. § 355(j)(5)(C)). It also relies on the amendment to the patent code, which provides that federal courts “shall, to the extent consistent with the Constitution, have subject matter jurisdiction” over declaratory judgment actions for a declaration of invalidity or non-infringement brought by ANDA applicants who have made a paragraph IV certification. (*Id.*).

Accordingly, Apotex asks the Court to disregard the reasonable apprehension test, and, instead to employ the Article III case or controversy analysis applied in non-patent

cases and in patent cases involving allegations of actual (as opposed to potential) infringement, requiring that “there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision.” (Pls.’ Mem. at 12) (citing *Bennett v. Spear*, 520 U.S. 154, 162, 167 (1997); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937); and *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003)). Apotex argues that the changes made by the Medicare Amendments require a similar analysis for ANDA-related declaratory judgment actions.

The argument is rejected. The Medicare Amendments do not disturb the Federal Circuit’s consistent holding that the constitutional limits of an Article III court’s jurisdiction in anticipatory patent infringement declaratory judgment actions are defined by the two-part reasonable apprehension test. *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361 (Fed. Cir. 2004); *Arrowhead*, 846 F.2d at 736; *Torpharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at \*7 (D. Del. June 28, 2004) (citing Medicare Amendments and holding reasonable apprehension test is “consistent with the Constitution”); *Glaxo Group Ltd. v. Dr. Reddy’s Labs., Ltd.*, 325 F. Supp. 2d 502, 507-08 (D.N.J. 2004). All of these decisions post-date the Medicare Amendments.

The legislative history of the Medicare Amendments supports the continued application of the reasonable apprehension test. The Conference Report accompanying the Medicare Amendments explains plainly, “the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a ‘reasonable apprehension’ of suit to establish jurisdiction.” H.R. Conf. Rep. No. 108-391, at 836 (2003).

In response, Apotex points to Congressional testimony reflecting a general intent to eliminate ANDA bottlenecks, arguing that jurisdiction in this case would effectuate that goal. (Pls.' Mem. at 9). While that may be true, it does not show that Congress intended to replace the well-established reasonable apprehension test for declaratory judgment patent cases with the analysis used in non-patent cases.

Accordingly, I apply the two-prong reasonable apprehension test.

### ***B. Application***

Pfizer does not dispute that the second prong of the reasonable apprehension test has been met. (See Def.'s Mem. at 10-20). By filing the ANDA, Apotex committed a "defined act of infringement sufficient to create case or controversy jurisdiction" in patent infringement actions. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Therefore I address only the first prong-whether Pfizer's conduct gave rise to a reasonable apprehension of suit.

Apotex has not shown that Pfizer created a reasonable apprehension of patent litigation, and thus no actual controversy exists. Therefore this Court does not have subject matter jurisdiction. The Court notes that two District Courts recently reached the same conclusion, in virtually identical cases involving the same patents and products at issue here. *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03-CV-10167 (RGS), 2003 WL 22888848 (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. 03-CV-726 (JAP), 2003 WL 21638254 (D.N.J. July 8, 2003). Likewise, courts in three other similar declaratory judgment cases also dismissed for lack of subject matter jurisdiction. *Torpharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756

(D. Del. June 28, 2004); *Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502 (D.N.J. 2004). *Mutual Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004).

As Pfizer has not explicitly threatened suit (Def.'s Mem. at 15), I consider the totality of the circumstances. See *Arrowhead*, 846 F.2d at 736. Apotex identifies four aspects of Pfizer's conduct that, taken together, allegedly give rise to a reasonable apprehension of suit: (1) Pfizer listed the '699 patent in the Orange Book, (2) Pfizer asserted the '699 patent against IVAX, (3) Pfizer has a history of litigating its patents, and (4) Pfizer has not acknowledged that Apotex's product does not infringe the '699 patent. (Pls.' Mem. at 21-25).

First, Pfizer's listing of the '699 patent in the Orange Book does not contribute to a reasonable apprehension of suit. According to the plain language of the law, an Orange Book listing represents merely that, in certain circumstances, an infringement claim "could" be asserted, but not that one will be asserted. 21 U.S.C. § 355(b)(1). An Orange Book listing imposes no obligation on the patent owner to sue, and does not suggest that a suit is expected or even likely. *Id.*; see *Torpharm, Inc.*, 2004 WL 1465756, at \*9 (finding that an Orange Book listing does not "communicate an intent to sue each and every generic who opts to file an ANDA"). Apotex compares the Orange Book listing to a private letter, noting that reasonable apprehension would exist if Pfizer had sent a letter to Apotex bearing the very same message. (Pls.' Mem. at 22). An Orange Book listing is unlike a private letter and does not carry the same threatening suggestion. An Orange Book listing is directed to the FDA, not any company in particular, and is submitted as a necessary element of the drug application. See 21 U.S.C. § 355(a), (b)(1).

Second, Pfizer's suit against IVAX does not contribute to a reasonable apprehension of suit. There was a distinct statutory incentive for Pfizer to sue IVAX: by suing the first filer within forty-five days of notice of the ANDA, Pfizer received an automatic thirty-month delay in the approval of that ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). There is no similar incentive for suing Apotex. Moreover, Pfizer has not sued any of the other ANDA applicants. (Myers Decl. ¶ 9).

Third, Pfizer's history of litigation, though lengthy, is not sufficiently related to this case to create a reasonable apprehension of suit. In cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, *Arrowhead*, 846 F.2d at 733; *Ivoclar Vivadent, Inc. v. Hasel*, No. 02-CV-0316E(F), 2003 WL 21730520, at \*1 (W.D.N.Y. June 30, 2003), or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology. *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953 (Fed. Cir. 1987); *Clontech Labs., Inc. v. Life Techs., Inc.*, No. Civ.A. AW-00-1879, 2000 WL 33124811, at \*1 (D. Md. Dec. 20, 2000); *SmithKline Beecham Corp. v. Zenith Goldline Pharms., Inc.*, No. Civ.A. 00-CV-1393, 2000 WL 963165, at \*1 (E.D. Pa. June 28, 2000). Apotex does not claim that Pfizer sent any threatening communication, but rather it relies on the fact that Pfizer has previously asserted its patent rights against other generic drug companies. (Pls.' Mem. at 24). What is missing from Apotex's argument, however, is an explanation as to how setraline hydrochloride is "essentially the same technology involved" in those actions. See *Goodyear Tire*, 824 F.2d at 954. Companies that profit largely from research and development will frequently find themselves involved in patent infringement litigation; what creates a reasonable apprehension of suit in any given case is

a relationship between that case and some prior litigation. Apotex has not established such a relation here.

Finally, Apotex asks the Court to consider Pfizer's refusal to acknowledge non-infringement, but Apotex does not explain how this behavior is threatening. (Pls.' Mem. at 25). At most, Pfizer's refusal is ambiguous; it does not affirmatively show an intent to sue.

### CONCLUSION

For the foregoing reasons, defendant's motion to dismiss for lack of subject matter jurisdiction is granted. The Clerk of the Court shall enter judgment dismissing the complaint without prejudice and close this case.

SO ORDERED.

**Appendix C – Opinion of the  
United States Court of Appeals for the Federal Circuit in  
*Teva Pharms. USA, Inc. v. Pfizer, Inc* (No. 04-1186)  
Filed January 21, 2005**

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UNITED STATES COURT OF APPEALS FOR THE  
FEDERAL CIRCUIT

No. 04-1186

TEVA PHARMACEUTICALS USA, INC., Plaintiff-  
Appellant,

v.

PFIZER, INC., Defendant-Appellee.

January 21, 2005.

Before MAYER\*, CLEVINGER, and SCHALL, Circuit  
Judges.

SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. In its ANDA, Teva sought the approval of the Food and Drug Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft® by Pfizer, Inc. ("Pfizer"). Pfizer holds

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\* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

two patents relating to Zolofit®: U.S. Patent No. 4,536,518 (the “’518 patent”) and U.S. Patent No. 5,248,699 (the “’699 patent”).

When Teva filed its ANDA, it also filed what is called in Hatch–Waxman parlance a “paragraph III certification.” In that certification, Teva stated that it would not market its generic drug until the ’518 patent expires. Simultaneously, Teva filed a Hatch–Waxman “paragraph IV certification.” In that certification, Teva stated that its generic drug did not infringe the ’699 patent or, alternatively, that the ’699 patent is invalid. The ’699 patent expires after the ’518 patent. Pursuant to the provisions of the Hatch–Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva’s paragraph IV certification to sue Teva for infringement of the ’699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer’s receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer’s ’699 patent or that the claims of the ’699 patent were invalid. On December 8, 2003, the district court dismissed Teva’s suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a).<sup>1</sup> *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03–CV–10167–RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

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<sup>1</sup> Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici,<sup>2</sup> we see no error in the district court's ruling that Teva failed to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

## BACKGROUND

### I.

#### A. *The Hatch–Waxman Amendments*

The Hatch–Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282). In the Amendments, Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

In order to speed up the approval process for generic drugs, the Amendments provide that a generic drug manufacturer

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<sup>2</sup> Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A). Under 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to engage in otherwise infringing acts necessary to prepare an ANDA. However, section 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. 35 U.S.C. § 271(e)(2).

The Hatch-Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted ...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

• Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the

factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(i). If the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month “stay” goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires. 21 U.S.C. § 355(j)(5)(B)(iii). During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. *Id.* If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. *Id.*

The first ANDA applicant to file a paragraph IV certification enjoys a 180-day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to “design around” patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 57 (July 2002). The 180-day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). The original Hatch–Waxman Amendments provided that the commencement of the 180-day exclusivity period could also be triggered by “the date of a decision of a court ... holding the patent which is the subject of the certification to be invalid or not infringed.”<sup>3</sup> *Id.*

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<sup>3</sup> As discussed in Part I.B., *infra*, in 2003 Congress enacted a more complex set of provisions relating to the 180-day exclusivity period. However, these new provisions do not apply in this case.

### B. *The 2003 Medicare Amendments*

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). Pursuant to that provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. *Id.* In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. *Id.* The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

Congress also addressed the statutory scheme surrounding the 180-day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180-day provisions. See 21 U.S.C. § 355(j)(5)(D) (Supp. 2004). However, the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003,

for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

## II.

### *A. The '518 and '699 Patents*

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression and anxiety disorders.<sup>4</sup> Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is directed to a novel crystalline form of sertraline hydrochloride and to a method for preparing it.<sup>5</sup> The commercial embodiment of the '518 and '699 patents is the drug Zoloft®, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual

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<sup>4</sup> The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent.

<sup>5</sup> The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

Report, Zoloft® generated revenues for the company in excess of \$2 billion in 2002.

*B. Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets*

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer of generic pharmaceuticals. In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the '518 and '699 patents in the Orange Book in connection with its NDA for Zoloft® tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. *Pfizer, Inc. v. Ivax Pharms. Inc.*, Nos. 00-408, 01-6007 (D.N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a position to begin marketing its generic version of Zoloft® immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv),

to a 180-day generic market exclusivity period. This 180-day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court ... holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II).

*C. Teva's ANDA filing relating to generic sertraline hydrochloride tablets*

As noted, in July of 2002, Teva submitted an ANDA to the FDA for its generic version of Zoloft®. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

*D. Teva's declaratory judgment action*

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its generic version of Zoloft® does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or

other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. See *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). The district court determined that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2) Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva. With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested interest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit

threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

## ANALYSIS

### I.

Our starting point is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), the statute under which Teva filed its suit. The Act provides in relevant part as follows:

In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Even if there is

an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. *Id.*; see also *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995) (reaffirming that since its inception, “the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants”). As we summarized in *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991): “When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary.”<sup>6</sup>

This court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. *EMC Corp.*, 89 F.3d at 811. The inquiry focuses on the conduct of both the patentee and the potential infringer. *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Id.*; *Amana Refrigeration*, 172 F.3d at 855; *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual

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<sup>6</sup> Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's declaratory judgment action. It is to the former question that we turn first.

## II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *Gen-Probe*, 359 F.3d at 1379. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed the '699 patent in

the Orange Book, thereby representing that the patent “could reasonably be asserted” against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45-days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement “*could* be reasonably asserted ....” 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. See *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) (“More is needed than knowledge or notice of an adversely held patent.... The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff.” (citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a

paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated that, "[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)). Although relevant to the analysis, neither of the factors upon which Teva relies is dispositive in this case. See *BP Chems.*, 4 F.3d at 980 ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal citation omitted)); *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985) ("The prior patent litigation initiated by Semi-Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable ....").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of *imminent* suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty*, 312 U.S. at 273. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." *Steel Co. v.*

*Citizens for a Better Env't*, 523 U.S. 83, 101 (1998). Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180-day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006. Because Teva is unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

### III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding ... that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced ...." Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory judgment provisions apply to this case.

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) so that it reads as follows:

Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, “consistent with the Constitution,” bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day period.<sup>7</sup>

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<sup>7</sup> Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension test serves “primarily prudential not constitutional concerns.” (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions such as this to the limits of Article III. Joined by Amicus Curiae the Federal Trade Commission (“FTC”), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180-day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft®. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft® market during the 180-day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In *EMC*, we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, “to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity.” 89 F.3d at 811. Teva, nevertheless, points to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. See *Arrowhead*, 846 F.2d at 736 (stating that the two-part test is a “test often useful in evaluating complaints for declaratory judgments in patent cases”); *Fina Oil Chem. Co. v. Ewen*,

123 F.3d 1466, 1470 (Fed. Cir. 1997) ("Satisfaction of th[e] traditional two-part test is not ... a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement."); *Hunier Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1327 (Fed. Cir. 1998) (stating that the two-part test "contributes to policing the boundary between a constitutional controversy ... and 'a difference or dispute of a hypothetical or abstract character.'" (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement. First, there is nothing in *Arrowhead* that supports that proposition. In *Arrowhead*, the court made clear that although the "actual controversy" test in suits requesting a declaration of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." *Arrowhead*, 846 F.2d at 737. At the same time, the statement from *Fina Oil* upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d at 1470. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met.<sup>8</sup> The statement in no way

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<sup>8</sup> In *Fina Oil*, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with 35 U.S.C. § 116 (1994). The statement relied upon by Teva merely reflects that the

suggests that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from *Hunter Douglas*, 153 F.3d at 1327, is really just another way of saying what we said in *EMC* in expounding on the traditional two-part test: “This court’s two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy.” 89 F.3d at 811. We would only add that we think this case presents just the sort of situation to which the *EMC* court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch–Waxman setting. The plain language of the amended statute—that courts shall have subject matter jurisdiction “to the extent consistent with the Constitution”—compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva’s. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S.1) in the 108th Congress, it was provided that the filing of a paragraph IV certification, and the failure of the patentee or NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

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precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories*, 289 F.3d 775, 784 (Fed. Cir. 2002). Judge Gajarsa suggested that “the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement.” *Id.* at 791. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R.1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R.1 states as follows:

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the “reasonable

apprehension” test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a “reasonable apprehension” of suit to establish jurisdiction. *See, e.g., Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch–Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. *See, e.g., Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002).<sup>9</sup> In any given case, the conferees

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<sup>9</sup> In *Vanguard Research*, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. 304 F.3d at 1254. The court held

expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391 at 836 (2003).

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's application of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger

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that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

the commencement of Ivax's 180-day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180-day exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft® with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft® market, not only from Ivax, but from other generic manufacturers as well. These circumstances, Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180-day exclusivity period following expiration of the '518 patent.

With these same considerations in mind, the FTC states that "while in a 'classic patent declaratory judgment suit,' the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting *Fina Oil*, 123 F.3d at 1466)), a case such as the present one presents a different situation: "[I]n the Hatch-Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17-18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not

established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed. Cir. 1986) ("The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'") (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576 (1982)). Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases. That is what we would have to do in order to rule in favor of Teva in this case. That is because, in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-a-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

## CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

## AFFIRMED

MAYER, Circuit Judge\*, dissenting.

Because the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will face a patent infringement suit, I respectfully dissent.

## I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed.

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\* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Cir. 1997). Under the Hatch–Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. § 156, 271, 282), part one is satisfied in every instance where an ANDA is filed in accordance with 21 U.S.C. § 355(j), because 35 U.S.C. § 271(e)(2) provides that such a filing constitutes an act of infringement sufficient to trigger a justiciable case or controversy. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–78 (1990) (determining that the purpose for creating an act of infringement in 35 U.S.C. § 271(e)(2) was to “eliminat[e] the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly”); *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

We have never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy. Conversely, we have consistently held that “there is no specific, all-purpose test” for determining the existence of a case or controversy, either. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735–36 (Fed. Cir. 1988) (describing the traditional two-part test as “often useful in evaluating complaints for declaratory judgments” but not mandatory in every instance). We have clarified that the “[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the ‘actual controversy’ requirement.” *Fina Oil*, 123 F.3d at 1470.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction."). "As in all cases our task is to interpret the words of [the statute] in light of the purposes Congress sought to serve." *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979).

## II.

Because Teva filed an ANDA pursuant to 21 U.S.C. § 355(j) against Pfizer's '699 patent listed in the Orange Book, our application of the traditional test for an "actual controversy" turns solely on whether Pfizer has taken actions that give rise to a reasonable apprehension that it will sue Teva for infringement. The trial court dismissed Teva's declaratory judgment claim saying that no "actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, No. 03-CV-10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

The 2003 amendments to the Hatch-Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117

Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(i)). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) (2003).

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201 (2000). This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. *See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement of 'injury in fact.'" *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 218 (1974) (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace*, 288 U.S. 249, 259 (1933), the Court determined that it should "look not to the label which the Legislature has attached to the procedure followed in the state courts, or to the description of the judgment which is brought here for review, in popular parlance, as 'declaratory,' but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in *Aetna Life Insurance Co. v. Haworth* decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory

judgments in appropriate cases. 300 U.S. 227 (1937). The Court “observed that the controversy would admit ‘of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’” *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998) (quoting *Aetna*, 300 U.S. at 241). Important to this case, the Court has “thus recognized the potential for declaratory judgment suits to fall outside the constitutional definition of a ‘case’ in Article III: a claim ‘brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs.’” *Id.* (quoting *Fairchild v. Hughes*, 258 U.S. 126, 129 (1922)). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch–Waxman and corresponding Medicare Amendments—the key issue being whether the courts are capable of achieving a final or conclusive determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed. Cir. 2004). The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *Id.* “Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required.” *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002) (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch–Waxman requires a thorough analysis of the consequences and repercussions of each party’s actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of any generic sertraline hydrochloride drug covered by the claims of the '699 patent. 21 U.S.C. § 355(b)(1) (2003). Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[ ] quiescent patent owners against unwarranted litigation." *Arrowhead*, 846 F.2d at 736. Pfizer is not a defendant that "has done nothing but obtain a patent." *Id.* By listing its patent in accordance with 21 U.S.C. §§ 355(b)(1) & (c)(2), Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch-Waxman establishes that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court ... holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv)(I-II). A

court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise. See *3M v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002). If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although Congress' intention was for Hatch-Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies to "park" the 180-day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45-day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i) 180 days after the first ANDA applicant enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180-day period. Essentially, the framework of Hatch-Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the relevant patent.

Taking into account the specific regulatory context of the Hatch–Waxman regime, the “reasonable apprehension” test applied “to the extent consistent with the Constitution” is satisfied by Pfizer’s conduct. See H.R. Conf. Rep. No. 108–391, at 836 (2003) (“[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a ‘reasonable apprehension’ of suit to establish jurisdiction” and the courts should “examine as part of their analysis the particular policies served by the Hatch–Waxman Act.”). Cases arising under Hatch–Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. See *Fina Oil*, 123 F.3d at 1470 (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch–Waxman regime, a subsequent ANDA applicant is not free to market—the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents and the likelihood of a future patent suit after the running of the 180-day period.

Against the backdrop of Hatch–Waxman, the totality of Pfizer’s conduct must also be considered. See H.R. Conf. Rep. No. 108–391, at 836 (2003) (“In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days].”). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer’s belief that its ‘699 patent is valid and its intent to assert the patent against infringers. “Related litigation may be evidence of a reasonable apprehension.” *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992). Pfizer also has a history

of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft®, produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.

**Appendix D – Opinion of the  
United States Court of Appeals for the Federal Circuit in  
*Teva Pharms. USA, Inc. v. Pfizer, Inc* (No. 04-1186),  
Denying Petition for Panel Rehearing  
and Rehearing *En Banc*  
Filed April 4, 2005**

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UNITED STATES COURT OF APPEALS FOR THE  
FEDERAL CIRCUIT

No. 04-1186

TEVA PHARMACEUTICALS USA, INC., Plaintiff-  
Appellant,

v.

PFIZER INC., Defendant-Appellee.

April 4, 2005.

ON PETITION FOR PANEL REHEARING AND  
REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER,  
LOURIE, CLEVINGER, RADER, SCHALL, BRYSON,  
GAJARSA, LINN, DYK, and PROST, Circuit Judges.

*ORDER*

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and a response thereto was

invited by the court and filed by the Appellee.<sup>1</sup> The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

- (1) The petition for panel rehearing is denied.
- (2) The petition for rehearing en banc is denied.
- (3) The mandate of the court will issue on April 11, 2005.

MAYER, GAJARSA, and DYK, Circuit Judges, would rehear the appeal en banc.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents in a separate opinion.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

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<sup>1</sup> Amicus curiae briefs were filed by:

1-The Federal Trade Commission.

2-The Generic Pharmaceutical Association.

3-Ivax Pharmaceuticals, Inc.

4-United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissenting from the order declining rehearing en banc.

The Court has denied the petition to review this case *en banc*. I must respectfully dissent from that denial. This is a critical issue under the Hatch-Waxman Act.<sup>1</sup> The failure of this court by *en banc* action to correct the *Teva* court's decision, 395 F.3d 1324 (Fed. Cir. 2005), allows the statutory procedures to be manipulated by the patent holders to the clear and foreseeable detriment of the generic drug industry.

The *Teva* court's reasonable apprehension analysis is the wrong test for a concrete, actual, or imminent injury in fact when considering the problem of a generic with a second-filed ANDA certification.<sup>2</sup> Article III does not compel it, and the Supreme Court has rejected the doctrinal rigidity that *Teva* introduces. Our cases recognize reasonable apprehension, in the typical patent infringement case, as but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law. The ANDA

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<sup>1</sup> The Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000)), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)).

<sup>2</sup> The overall scheme of the Hatch-Waxman Act is described in detail in our decisions in *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

facts correspond to the typical infringement case in name only, and it is this court's constitutional duty to look at those facts in their proper context. The *Teva* court's misguided Article III analysis further thwarts Congress's clear intent to foster, through the detailed provisions of Hatch-Waxman, greater competition in generic pharmaceuticals.

I.

The question is whether Teva has shown a justiciable case or controversy within Article III. Congress unambiguously swept aside any additional limitation on jurisdiction potentially introduced by the Declaratory Judgment Act, 28 U.S.C. § 2201.

[T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C.A. § 271(e)(5) (West Supp. 2004), as added by Pub. L. 108-173, 117 Stat. 2457 (Dec. 8, 2003). The law is clear that this justiciability issue has three elements: (1) a concrete, actual or imminent injury in fact; (2) fairly traceable causation between the injury and defendant's conduct; and (3) redressability. See *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998); *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982). Only the concrete injury in fact is disputed.

The cases treat the controversy requirements of Article III and § 2201 together and their approach is instructive here. Jurisdiction under § 2201 can be no broader than jurisdiction under Article III, yet the cases show that § 2201 is very broad indeed. Article III is no narrower. See *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 240 (1937) (§ 2201 "has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense[.]"). As the Supreme Court recognizes, the § 2201 controversy requirement is highly fact specific.

The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

*Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). The Supreme Court,<sup>3</sup> this court,<sup>4</sup> and our sister

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<sup>3</sup> See *Steel Co.*, 523 U.S. at 103-04; *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 81 (1978) (finding actual case and controversy where plaintiffs would sustain injury from operation of planned nuclear power plant, and injury was redressable by constitutionality challenge to Price-Anderson Act).

<sup>4</sup> See *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996)

circuits<sup>5</sup> consistently apply this holding by looking to all the circumstances surrounding a controversy.

### A.

The *Teva* majority opinion does not, and its reasons for failing to do so are not convincing. In far more difficult factual contexts the courts have nonetheless found “a concrete, actual or imminent injury in fact” satisfying Article III. In *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59 (1978), for example, the appellees challenged the constitutionality of the Price-Anderson Act. By that Act, Congress limited the aggregate tort liability of nuclear power plant operators for a single nuclear “incident.” The appellant was a utility that was *constructing* nuclear power plants. The appellees, including persons “who live within close proximity of the *planned* facilities,” challenged the statute under the Fifth Amendment. *Id.* at 67 (emphasis added). Their theory was that “*in the event of a nuclear accident their property would be ‘taken’ without any assurance of just compensation.*” *Id.* at 69 (emphasis added). The court concluded that this theory stated a justiciable Article III controversy. See *id.* at 81 (“[A]ppellees will sustain immediate injury from the operation of the disputed power plants.”).

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(quoting *Md. Cas.*), *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) (“There is no simple rule that addresses all shades of relationships between disputants.”); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing “there is no specific, all-purpose test” for an actual controversy).

<sup>5</sup> See, e.g., *Riva v. Mass.*, 61 F.3d 1003, 1009-10 (1st Cir. 1995); *Kidder, Peabody & Co., Inc. v. Maxus Energy Corp.*, 925 F.2d 556, 562-63 (2d Cir. 1991); *Oneida Tribe of Indians of Wis. v. State of Wis.*, 951 F.2d 757, 760 (7th Cir. 1991).

The breadth of Article III standing in environmental cases sharply contrasts with the *Teva* court's narrow construction in this ANDA context. The Supreme Court has held that a concrete injury in fact, for Article III, is shown where a non-profit's members allege that a polluter's discharges, "and the affiant members' *reasonable concerns about the effects* of those discharges, directly affected those affiants' recreational, aesthetic, and economic interests." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 183-84 (2000) (emphasis added). The Court expressly ruled that conditional statements—that members would use a river for recreation if Laidlaw stopped discharging pollutants into it—sufficed to show concrete injury in fact under Article III. *Id.* at 184. *Teva's* injury in this case, by comparison, is far more immediate.

The facts showing *Teva's* "concrete, actual or imminent injury" are far easier to identify. Ivax filed the first ANDA on the active ingredient for Zolof; *Teva* filed a subsequent or second ANDA. *Teva* certified that its proposed formulation would not infringe Pfizer's U.S. Patent No. 5,248,699, or that the patent was invalid. Pfizer had 45 days to sue *Teva* for this patent infringement, 35 U.S.C. § 271(e)(2)(A), and did not. Although Pfizer had sued Ivax, they settled out of court. Pfizer granted Ivax a royalty bearing license for the '699 patent, preserved Ivax's 180 day statutory exclusivity, and designed a comfortable duopoly set to begin on June 30, 2006 and potentially last 180 days past the '699 patent expiration in 2010. The FDA therefore could not approve *Teva's* generic drug until 180 days after Ivax's exclusivity expired—when either the '699 patent expired or was invalidated—and without FDA approval *Teva* could not market its product.

By settling with Ivax, Pfizer leveraged the Hatch-Waxman exclusivity to insulate the '699 patent from any validity challenge. Pfizer also insulated itself from any judicial determination of the metes and bounds of its '699 patent claim scope in relation to a design-around, a determination central to the proper function of our patent system. Because of this insular effect, Pfizer effectively extended—as against all but Ivax—the term of its underlying U.S. Patent No. 4,356,518, which expires on June 30, 2006, to coincide with the '699 patent's later expiration in 2010.<sup>6</sup>

This ties up Teva's investment in its proposed generic until at least 2010, precludes it from testing a potentially weak patent, precludes it from triggering the statutory exclusivity period with a successful validity challenge, and precludes it from introducing an effective design-around, as is its right and as the patent law encourages. The live controversy is found on the face of this bottleneck under the statute.<sup>7</sup> Any of this defines a concrete, actual or imminent injury in fact

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<sup>6</sup> That is, the '518 patent claims the active ingredient in Zoloft. The '699 patent is an improvement. A generic, like Teva, that could design around the '699 but not the '518—or that thought it had found invalidating art for the '699 patent—would need a license to the '518 patent to enter the market, or face an infringement action. Once the '518 patent expired, Teva could confidently enter the market with a compound that did not infringe the '699 patent. But because of the Hatch-Waxman exclusivity, Pfizer insulated the '699 patent from any test in litigation. In practice this extends the '518 patent term until the '699 patent expires.

<sup>7</sup> Cf. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n. 18 (D.C. Cir. 1998) ("It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.").

within the meaning of Article III, and on that basis Teva states a justiciable controversy under § 2201.

B.

None of these problems can be found in the typical patent infringement context, in which this court has regularly tested immediate injury in fact by the reasonable apprehension test. Consistent with *Maryland Casualty*, this court has never held that Article III required that analysis. Quite to the contrary, this court has repeatedly observed that reasonable apprehension was simply a functional approach to typical patent infringement problems under § 2201. See *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy). The purpose of the reasonable apprehension analysis "is to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The *Teva* court ignores this precedent and reads general infringement policy considerations into Article III, where they do not belong.

The contextual differences between the second ANDA filer and the typical patent infringement case make the reasonable apprehension test inappropriate for this action. By guiding the patentee's conduct in the typical case, the reasonable apprehension analysis allows the patentee to avoid litigation. Identifying a justiciable controversy in terms of a threat of infringement litigation, the doctrine establishes the circumstances in which the uncertainty of legal rights materially harm a potential infringer in the marketplace. The

injury facing Teva in this case is different in kind, but no less actionable.

Teva's injury does not depend on threats from the incumbent. In view of the statute, the injury exists independent of any threat, and the policy motivation for applying the reasonable apprehension test is completely lacking. There is no sense in the court demanding the incumbent to brandish the threat of infringement actions, even beyond the act of listing a patent in the Orange Book, given a statutory system that encourages the incumbent to do everything possible to prevent its patents from being put in play. No incumbent will ever make the threat, if it can simply ride out the term in the listed patent.<sup>8</sup> From first principles, a fact specific analysis shows that the reasonable apprehension test is not designed for this case.

## II.

The language of § 271(e)(5) grants Article III jurisdiction to the maximum extent possible. The statute provides that the courts shall *have* subject matter jurisdiction. The majority's analysis in *Teva* of the legislative history to the 2003 Act<sup>9</sup> seems addressed to this point, but its reasoning is unconvincing.

The statute specifically provides that the courts “shall, to the extent consistent with the Constitution, have subject matter

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<sup>8</sup> See *Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002).

<sup>9</sup> Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)) [hereinafter “2003 Act”].

jurisdiction in any action.” The court, therefore, has a Congressional directive to refrain from applying any jurisdictional limitation crafted by the courts or found in § 2201. The *Teva* court overlooks this basic point.

The *Teva* court further focuses on the language originally introduced for § 271(e)(5), which provided that an incumbent's failure to sue within 45 days “shall establish an actual controversy between the applicant and the patent owner.” *Teva*, 395 F.3d at 1336. In conference the language was changed to a provision that the courts “shall, to the extent consistent with the Constitution, have subject matter jurisdiction” over these actions. *Id.* The court concludes that § 271(e)(5) was “not meant to automatically bestow district court jurisdiction over actions such as *Teva*’s.” *Id.* This conclusion is contrary to the plain language of § 271(e)(5). The change in language bestowed full Article III jurisdiction and simply recognizes the court's role in declaring when the judicial powers under Article III extend to this action. It does not bear on the proper scope of Article III.

The *Teva* court also focuses on a Committee Report accompanying the modified 2003 Act. The language in the Report cannot contradict the plain language of § 271(e)(5). A legislative enactment cannot limit the judicial power under Article III, and, *a fortiori*, language in a Committee Report that misstates our Article III jurisprudence cannot bind this court.

Ultimately, the idea that § 271(e)(5) suggests a limitation on standing is misplaced, given the plain language of Hatch-Waxman. The statute provides an express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents. Under this statutory

scheme, it is court challenges by generic drug companies that limit incumbent overreaching by submitting over-inclusive lists of patents applicable to any given branded formulation. Congress's intent to foster early generic market entry precludes any real argument for any limitation. Certainly under the circumstances of this case, Teva's declaratory action is the ideal method to police Pfizer's strategic manipulation of the Hatch-Waxman exclusivity provisions. Delayed resolution of the bottleneck facing Teva serves no purpose, as by then the patents at issue will have expired. There is no basis for precluding this suit on Article III grounds.

### III.

The *Teva* court's Article III analysis distorts longstanding Supreme Court jurisprudence and misapplies the decisions of this court. Teva has presented a justiciable controversy, and the courts should decide it. Worst of all, the *Teva* court's Article III analysis forestalls legislative correction. The court should have corrected this error *en banc*. I respectfully dissent from the refusal to do so.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissenting from the order denying rehearing en banc.

This case presents an important question under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000))—whether a patent holder can delay Food and Drug Administration (“FDA”) approval of an application for a competing generic drug by the simple expedient of refusing

to sue for infringement. Here there is a present controversy over Teva's right to secure approval of its Abbreviated New Drug Application ("ANDA"), plainly adequate to satisfy the requirements of Article III.

The Declaratory Judgment Act, 28 U.S.C. § 2201 (2000), and the 2003 Medicare Amendments, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat. 2066, 2448-69 (codified in pertinent part at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)), were designed to create a declaratory judgment remedy in circumstances permitted by Article III. The panel's holding, relying on earlier decisions of our court, that Article III bars such a remedy unless "a reasonable apprehension of *imminent* suit" exists is incorrect. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). I dissent from the denial of rehearing *en banc*.

# I.

The plain language of the 2003 Medicare Amendments requires that in the Hatch-Waxman context the federal courts allow declaratory judgment actions to the full extent allowed by Article III. 35 U.S.C.A. § 271(e)(5) ("[C]ourts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). Even if the legislative history could be read as approving our reasonable apprehension test, that history cannot overcome the plain language of the statute. So we must decide whether Article III is satisfied.

There are relatively few Supreme Court cases dealing with Article III and declaratory judgments, but the few cases that do exist provide no support for a reasonable apprehension of imminent suit requirement. The declaratory judgment statute was designed to deal with a situation in which the declaratory judgment defendant declined to bring suit, i.e., in which there was no reasonable apprehension of imminent suit. The Supreme Court case upholding the statute involved just such a situation—one in which there was no imminent risk of suit because the potential plaintiff declined to sue. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937). In that case, the insured on several policies stopped making premium payments and made repeated claims for benefits on account of total and permanent disability. *Id.* at 237-38. Aetna refused to pay benefits because it contended that the insured was not disabled and that the policies had lapsed due to nonpayment. *Id.* at 238. The insured failed to bring suit, so Aetna filed for a declaratory judgment that the insured was not disabled and that the policies had lapsed. *Id.* at 239. The Court found that these facts gave rise to a controversy within the meaning of Article III, stating “[t]here is here a dispute between parties who face each other in an adversary proceeding.... The dispute is defined and concrete, not hypothetical or abstract.... It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts.” *Id.* at 242.

Likewise, the Ninth Circuit, in a case in which the plaintiff faced a risk of liability rather than suit, has held that “[a]n action for a declaratory judgment ... is a case or controversy if the plaintiff has a real and reasonable apprehension that he will be subject to *liability*,” not suit. *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co., Inc.*,

655 F.2d 938, 944 (9th Cir.1981) (emphasis added).<sup>1</sup> The First Circuit has even more directly addressed the issue in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), and adopted a view that conflicts with the panel decision in this case. There, a World Intellectual Property Organization ("WIPO") panel found Sallen to be a cybersquatter and ordered his domain name transferred to Corinthians Licenciamentos LTDA ("CL"). *Id.* at 21-22. Sallen filed suit in federal district court seeking a declaration that under United States law (which allowed a challenge to the WIPO decision) he was entitled to the domain name. *Id.* at 22. The district court dismissed the case because CL had no intent to sue Sallen under United States law. *Id.* On appeal, the First Circuit rejected CL's argument that a reasonable apprehension of suit is required to satisfy Article III:

CL claims that a reasonable apprehension of suit is required to meet Article III's case or controversy requirement. *But this is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit. That is not this case.*

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<sup>1</sup> That case involved a manufacturer that filed for declaratory judgment of invalidity of the defendant's patent after a potentially unauthorized person working for the defendant threatened a third party with suit if the third party purchased the plaintiff's equipment. *Id.* at 941, 944-45. The third party purchased the equipment. *Id.* at 941. A hold harmless provision in the contract between the third party and the plaintiff placed the plaintiff in reasonable apprehension of liability. *Id.* at 945.

*Id.* at 25 (internal citations omitted and emphasis added). The court found that United States law “provides a registrant who has lost a domain name ... with a cause of action for an injunction returning the domain name if the registrant can show that she is in compliance with” United States law. *Id.* at 26. Thus, the court found that the controversy in issue was certain and that “a certain controversy renders the ‘reasonable apprehension’ question irrelevant.” *Id.*

In my view, the First Circuit is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test. The panel here also reached the wrong result in this case by relying on that erroneous test.

## II.

Here it seems to me that there are three potential controversies:

1. There is a potential controversy over whether the ANDA filing itself was an infringement. I doubt whether this, standing alone, satisfies Article III because Pfizer seems not to care whether such an infringement occurred. *Textron Lycoming Reciprocating Engine Div., AVCO Corp. v. UAW*, 523 U.S. 653, 661 (1998) (finding no constitutional controversy where the declaratory judgment defendant had no “interest in defending the binding nature of the contract”).

2. There is also a potential controversy over whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement. The problem here is that Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from doing so by the risk of infringement

damages. Instead, Teva alleges only that the filing of its ANDA constituted technical infringement; that Pfizer did not file suit within the 45-day period; that Pfizer included the '699 patent in the Orange Book; and that Pfizer tends to enforce its patents through litigation. (J.A. at 52.) Unless Teva actually is about to manufacture or sell the drug, there would seem to be no case or controversy under this theory. *Societe de Conditionnement*, 655 F.2d at 944.

3. The third potential controversy is over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing. In my view, there is a present and concrete controversy over Teva's right to such an approval, which satisfies the requirements of Article III. The Hatch-Waxman Amendments provide for the right to secure resolution of the controversy through a declaratory judgment.

Ivax earlier filed a paragraph IV certification regarding the '699 patent and then settled with Pfizer. Thus, Ivax will enjoy a 180-day exclusivity period beginning with the *earlier* of (1) the first day it markets its generic drug (which cannot be earlier than June 30, 2006) or (2) the date that the '699 patent is held invalid or not infringed in the decision of a court.<sup>2</sup> Because of the paragraph IV certification, Teva's application cannot be approved by the FDA until after Ivax's 180-day exclusivity period ends. *Teva*, 395 F.3d at 1328, 1330. In other words, the running of the exclusivity period

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<sup>2</sup> To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section, but despite Pfizer's failure to sue, 21 U.S.C. § 355(j)(5)(B)(iv) will bar approval until 180 days after Ivax markets the drug unless there is an earlier holding of non-infringement or invalidity.

could be triggered before Ivax's first marketing date if Teva could secure a declaratory judgment of non-infringement or invalidity. Approval of Teva's ANDA would follow 180 days thereafter.

Normally, one would expect that the approval issue would be litigated between Teva and the FDA, but, as we recognized in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002), Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity.<sup>3</sup> There is certainly a concrete controversy between Pfizer (and Ivax) and Teva over when Teva's ANDA should be approved. Both Pfizer and Ivax want the approval of Teva's application delayed. Teva wants to avoid delay. The question of delay turns on infringement and validity.<sup>4</sup> Under these circumstances, I think there is a case or controversy within the meaning of Article III, and that the questions of infringement and validity should be addressed. The panel appears to recognize the existence of a controversy, but holds that the controversy is insufficient for purposes of Article III.<sup>5</sup> I respectfully disagree. Under the

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<sup>3</sup> See also *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

<sup>4</sup> While the '518 patent imposes an additional limitation on the approval of Teva's ANDA such that it could not be approved until the '518 patent expires (June 30, 2006), it is hardly premature to litigate the approval date since litigation over infringement and invalidity of the '699 patent could itself consume a significant time.

<sup>5</sup> The panel states that "[t]he fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from

panel's decision Teva lacks any remedy to contest the delay in its ANDA approval. I agree with Judge Mayer and Judge Gajarsa that Article III does not require such unfairness.

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whether an Article III controversy exists between Teva and Pfizer.”  
*Teva*, 395 F.3d at 1338.

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**Appendix E – U.S. CONST., art. III, § 2**

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**CONSTITUTION OF THE UNITED STATES****ARTICLE III**

**Section 2.** The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies to which the United States shall be a Party;--to Controversies between two or more States;--between a State and Citizens of another State;--between Citizens of different States;--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

**Appendix F – 21 U.S.C.A. § 355(j)(5)(C)**  
**(West Supp. 2005)**

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**TITLE 21 – FOOD AND DRUGS**  
**CHAPTER 9 – FEDERAL FOOD, DRUG, AND**  
**COSMETIC ACT**

**SUBCHAPTER V – DRUGS AND DEVICES**

**PART A – DRUGS AND DEVICES**

**§ 355. New drugs**

**\* \* \***

**(j) Abbreviated new drug applications**

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**(5) \* \* \***

**(C) Civil action to obtain patent certainty**

**(i) Declaratory judgment absent infringement  
action**

**(I) In general**

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

**(aa)** the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

## **(II) Filing of civil action**

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

**(III) Offer of confidential access to application**

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

**(ii) Counterclaim to infringement action****(I) In general**

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either--

**(aa)** the drug for which the application was approved;  
or

**(bb)** an approved method of using the drug.

**(II) No independent cause of action**

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

**(iii) No damages**

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

**Appendix G – 35 U.S.C.A. § 271(e)(5) (West Supp. 2005)****TITLE 35 – PATENTS****PART III – PATENTS AND PROTECTION OF PATENT  
RIGHTS****CHAPTER 28 – INFRINGEMENT OF PATENTS****§ 271. Infringement of patent**

\* \* \*

(e) \* \* \*

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.